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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,852	08/17/2000	Alissar Nehme	600-41-PA	5392

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EXAMINER
LANDSMAN, ROBERT S

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 10/25/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/640,852	Applicant(s) NEHME ET AL.	
	Examin r Robert Landsman	Art Unit 1647	

-- The MAILING DATE of this communication appears on th cover she t with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5,6,9,10,13-16,19-21,24-27 and 30* is/are rejected.

7)☒ Claim(s) *3, 4, 7, 8, 11, 12, 17-18, 22, 23, 28 and 29* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Formal Matters

A. Amendment A, filed 7/16/02, has been entered into the record.

B. Claims 1-30 are pending in this application and are the subject of this Office Action.

C. All Statues under 35 USC not found in this Office Action can be found, cited in full, in a previous Office Action.

2. Claim Objections

A. The objection to claim 1 has been withdrawn since Applicants have amended the claim to include a semicolon.

B. The objection to claim 1 has been withdrawn since Applicants have amended the claim to include commas around the word "independently."

C. Claims 3, 4, 7, 8, 11, 12, 17, 18, 22, 23, 28 and 29 remain objected to under 37 CFR 1.75 as being substantial duplicates of claims 2, 6, 10, 15, 21 and 27 as stated on page 3 of the Office Action dated 2/13/02. Applicants argue that all these claims, which recite compositions for treating specific malignant diseases such as breast cancer and leukemia, are species of generic claims which recite compositions for treating malignant diseases. Therefore, these claims are not duplicates. This argument has been considered, but is not deemed persuasive. Though Applicants do recite that these compositions are to be used to treat specific versus general diseases, Applicants have not recited any limitations in these species claims which differentiate them from the generic claims. Applicants have only stated that the compositions are to be used (i.e. "adapted") for different purposes (i.e. treating different diseases). However, there are no further limitations (e.g. other substances in the composition) in the species claims to differentiate the compositions from those in the generic claims. Therefore, according to the claims, since the composition of each of these claims comprises the same substances, with no recited "adaptations," the claims are substantial duplicates.

D. Claims 3, 4, 7, 8, 11, 12, 17, 18, 22, 23, 28 and 29 are objected to since they depend from claims 1, 2, 5, 6 9, 10, 13-16, 19-21, 24-27 and 30, which are rejected under 35 USC 112, first paragraph, for the reasons set forth below.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

A. Claims 1, 2, 5, 6, 9, 10, 13-16, 19-21, 24-27 and 30 remain rejected under 35 USC 112, first paragraph, for the reasons already of record on pages 3-5 of the Office Action dated 2/13/02. Applicants argue that this rejection should be made under 35 USC 101 and that in vitro testing data clearly show positive results and thus demonstrates utility and enables the present invention. In fact, the in vitro data disclosed in the instant application do demonstrate a utility of the present invention and it is for this reason that a rejection under 35 USC 101 was not made. The issue is one of scope of enablement. Applicants are claiming a method of treating any and all malignant diseases using the compound of the invention. However, page 9, lines 10-12 of the specification only define 3 cell lines which were used to demonstrate the effectiveness of the claimed compounds, SK-BR-3, T-47D and HL-60 cells. These three cells represent only breast cancer and leukemia cell lines. In fact, all of the data shown in the Figures only demonstrates that the claimed compound shown effects in these three cell lines, which is only a small representation of the possible number and types of malignant diseases. Applicants have not provided and guidance or working examples of the use of this compound for treating any diseases (e.g. solid tumors) other than breast cancer and leukemia. Therefore, it would not be predictable to one of ordinary skill in the art for which malignant diseases, including solid tumors, the claimed compound would be expected to treat, nor would it be predictable for which malignant diseases, other than breast cancer and leukemia, the claimed compounds would be expected to be functional.

Therefore, in summary, due to the excessive breadth of the claims regarding pharmaceutical compositions which can be used to treat any and all malignant diseases (e.g. solid tumors) other than breast cancer and malignant blood diseases such as leukemia, combined with the lack of guidance and working examples of malignant diseases other than breast cancer and these malignant blood diseases as well as the lack of predictability as to which other malignant disease other than breast cancer and malignant blood diseases, would be expected to be treated by the compound of the present invention, leads the Examiner to maintain that undue experimentation would be required to practice the invention as claimed. It is believed that all pertinent arguments have been addressed.

4. Claim Rejections - 35 USC § 112, second paragraph

A. The rejection of claims 1 and 14 under 35 USC 112, second paragraph, has been withdrawn since Applicants have amended the claims to define the variable "X."

B. The rejection of claims 1 and 14 under 35 USC 112, second paragraph, has been withdrawn in view of Applicants' arguments that the daily dose of the pharmaceutical composition is based on the nature and severity of the disease and can be determined through routine experimentation.

5. Claim Rejections - 35 USC § 103

A. The rejection of claims 1-3, 5-7, 9-11, 13-17, 19-22, 24-28 and 30 under 35 USC 103 has been withdrawn in view of Applicants amendments to the claims to recite that the claimed composition shows synergistic effect. These effects could not be rendered obvious by the prior art.

6. Conclusion

A. No claim is allowable.

B. Claims 3, 4, 7, 8, 11, 12, 17, 18, 22, 23, 28 and 29 are free of the prior art and would be allowable once the issue of being substantial duplicates of one another is resolved.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.
Patent Examiner
Group 1600
October 22, 2002

Gary L Kunz
GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600